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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,653	10/15/2001	Mark Thompson	MA-702D2	4237

23557 7590 04/23/2003

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EXAMINER

PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. .

09/977,653

Applicant(s)

Thompson et al.

Examiner

Rebecca Prouty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 7-12, 14, and 16-21 is/are pending in the application.
- 4a) Of the above, claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 9-12, 16, 18, and 19 is/are rejected.
- 7) ☒ Claim(s) 5, 8, 14, and 17 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Claims 4, 6, 13, and 15 have been canceled. Claims 1-3, 5, 7-12, 14, and 16-21 are at issue and are present for examination.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 5, 7-12, 14, and 16-19, drawn to truncated Cry6A toxins and methods of use, classified in class 514, subclass 12.
- II. Claims 20 and 21, drawn to nucleic acids and host cells encoding truncated Cry6A toxins, classified in class 435, subclass 252.3.

The inventions are distinct, each from the other because of the following reasons:

The DNA of Group II and the proteins of Group I are patentably distinct compounds because they are chemically different, the DNA has other utility besides encoding the proteins such as a hybridization probe and the proteins can be made by another method such as isolation from natural sources and protease digestion or chemical synthesis.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their different classification, restriction for examination purposes as indicated is proper.

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During a telephone conversation with Jay Sanders on 4/17/03 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-3, 5, 7-12, 14 and 16-19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20 and 21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 7, 9, 16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are indefinite in the recitation of "approximately amino acid 11 to approximately amino acid 443 (or 390)" as the metes and bounds of what fragments of SEQ ID NO:2 are encompassed is unclear. For example how is the scope of Claim 7 different from Claim 1 (any pesticidal fragment of amino

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acids 2-443 of SEQ ID NO:2) and Claim 5 (amino acids 11-443 of SEQ ID NO:2). For purposes of examination Claims 7 and 9 will be treated as identical to Claims 1 and 3 respectively and Claims 16 and 18 will be treated as identical to Claims 10 and 12 respectively.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 7, 9-12, 16, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Payne et al. (US Patent 5,262,159) in view of Aronson et al., Nagamatsu et al., Pfannenstiel et al., Nicholls et al. and Wakibo et al.

Payne et al. teach the 86A1 (Cry6A) toxin. Payne et al. further teach fragments of the 86A1 toxin and recite a generic

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formula of active toxins which particularly includes sequences corresponding to the amino terminus through amino acid 390 of the 86A1 toxin but lacking any sequence carboxy terminal thereto. (see particularly column 5) and protease digestion of the 86A1 toxin (column 7). Payne et al. do not specifically teach truncations at the amino terminus.

The combined disclosures of Aronson et al., Nagamatsu et al., Pfannenstiel et al., Nicholls et al. and Wakibo et al. show that it is well known in the art to produce truncated Bt toxins by either recombinant production or protease digestion of the toxins and that toxin fragments of the amino terminal region of a wide variety of Bt toxins exhibit insecticidal activity. Furthermore, the combined disclosures of these references show that protease digestion of Bt toxins to a insecticidal protease resistant core protein, usually produces small truncations at the amino termini (usually on the order of 10-100 amino acids) and large carboxy terminal deletions in a wide variety Bt toxins.

Therefore, it would have been obvious to one of ordinary skill in the art to make truncated the 86A1 toxins as explicitly suggested by Payne et al. by protease digestion of the 86A1 toxin and/or by recombinant production. Furthermore, one of ordinary skill in the art would reasonably expect that amino terminal truncations of up to approximately 10 amino acids as well as

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carboxy terminal deletions of all amino acids not included within the generic formula of Payne et al. to maintain the insecticidal activity in view of the combined disclosures of the prior art. One would have been so motivated as the skilled artisan would have been well aware that truncated Bt toxins are usually expressed substantially better in recombinant plants than the corresponding full length protoxins.

Claims 5, 8, 14, and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

While as discussed above, the prior art suggests protease digestion of the 86A1 toxin to an insecticidal protease resistant core protein, and provides a reasonable expectation that the core would include small N-terminal deletions as well as C-terminal deletions of at least 85 amino acids, the prior art shows that the exact extent of deletions that can be made is unpredictable (particularly in this case with respect to the N-terminus) and therefore selection of the specific fragments of SEQ ID NO:2 recited in these claims would have been at best obvious to try. Furthermore, it should be noted that the specification establishes that the toxin of SEQ ID NO:6 has unexpectedly superior toxicity to corn rootworms than the full length 86A1

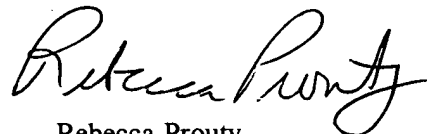
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toxin. This is further evidence of the non-obviousness of this specific toxin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rebecca Prouty
Primary Examiner
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